

**In-stent Restenosis and Stent Thrombosis***Moscone West, 1st Floor***Tuesday, October 29, 2013, 3:30 PM–5:30 PM**

Abstract nos: 447-485

**TCT-447****Predictors and clinical implications of stent thrombosis in patients with ST-segment elevation myocardial infarction. Insights from the EXAMINATION trial**

Salvatore Brugaletta<sup>1</sup>, Manel Sabate<sup>2</sup>, Victoria Martin-Yuste<sup>3</sup>, Monica Masotti<sup>4</sup>, Angel Cequier<sup>5</sup>, Armando Bethencourt<sup>6</sup>, Josep Gomez Lara<sup>7</sup>, Andres Iñiguez<sup>8</sup>, Antonio Serra<sup>9</sup>, Rosana Hernandez-Antolin<sup>10</sup>, Marco Valgimigli<sup>11</sup>, Vicente Mainar<sup>10</sup>, Maurizio Tespili<sup>12</sup>, Nicolas Vazquez<sup>13</sup>, Peter den Heijer<sup>14</sup>, Patrick W. Serruys<sup>15</sup>

<sup>1</sup>Clinic Thorax Institute, Barcelona, Spain, <sup>2</sup>University of Barcelona, Barcelona, Spain, <sup>3</sup>Hospital Clinic, Barcelona, Spain, <sup>4</sup>H Clinic Barcelona, Barcelona, Spain, <sup>5</sup>Hospital de Bellvitge, Barcelona, Spain, <sup>6</sup>Hospital Son Espases, Palma de Mallorca, Spain, <sup>7</sup>Hospital Universitari de Bellvitge, Hospitalet de Llobregat, Spain, <sup>8</sup>Hospital de Vigo, Vigo, Spain, <sup>9</sup>Hospital de Sant Pau y Santa Creu, Barcelona, Spain, <sup>10</sup>Hospital Universitario Ramón y Cajal, Madrid, Spain, <sup>11</sup>University Hospital of Ferrara, Ferrara, Italy, <sup>12</sup>University Hospital Bolognini Seriate, Bergamo, Italy, <sup>13</sup>Hospital Juan Canalejo, A Coruña, Spain, <sup>14</sup>Amphia Hospital Breda, Breda, NB, <sup>15</sup>Thoraxcenter-Erasmus University, Rotterdam, Netherlands

**Background:** few data are available about safety of second generation drug eluting stents in an all-comer ST elevation myocardial infarction (STEMI) population. We sought to investigate the predictors and clinical implications of 1-year stent thrombosis (ST) in patients with STEMI, included the EXAMINATION trial.

**Methods:** The EXAMINATION trial is an all-comer prospective, randomized 1:1 controlled trial, testing everolimus-eluting stent (EES) vs. cobalt chromium bare metal stent (BMS) in STEMI patients. It included 1498 patients, randomized to EES (n=751) or BMS (n=747). **Results:** At 1-year, definite/probable stent thrombosis, defined according to ARC criteria, occurred in 26 patients (1.73%), including 18 definite and 8 probable events. The incidence of ST was lower in patients treated with EES than in those treated with BMS (HR 0.16, 95% CI 0.03 – 0.29, p=0.017). Patients with ST have higher 1-year rates of cardiac death (30.8% vs. 2.5%, p<0.001), myocardial infarction (30.8% vs. 0.5%, p<0.001) and target vessel revascularization (65.4% vs. 4.2%, p<0.001) compared with those without. Independent predictors of 1-year definite/probable ST were BMS implantation at the index procedure (HR 3.41, 95% CI 1.35–8.60), ST segment resolution of at least 70% in the EKG post-PCI (HR 0.30, 95% CI 0.13–0.70) and Killip class on admission (HR 2.57, 95% CI 1.70–3.90).

**Conclusions:** ST had low frequency in the first year after implantation of EES/BMS in STEMI patients, but it is associated with adverse events. BMS implantation, lack of ST-segment resolution and high Killip class on admission were independent predictors of 1-year ST.

**TCT-448****Long-Term Clinical Results Of SeQuent Please Paclitaxel-Coated Balloon Angioplasty For The Treatment Of In-Stent Restenosis**

Javier Benezet<sup>1</sup>, Ignacio Sanchez-Perel<sup>1</sup>, Fernando Lozano<sup>1</sup>, Felipe Higuera<sup>1</sup>, Natalia Pinilla<sup>1</sup>, Yasser Hessein<sup>1</sup>

<sup>1</sup>Hospital General Universitario de Ciudad Real, Ciudad Real, Spain

**Background:** Paclitaxel-coated balloons (PCB) have been proven to be effective for the treatment of coronary in-stent restenosis (ISR) after bare-metal stent (BMS) or drug-eluting stent (DES) implantation. This study aims to evaluate the long-term safety and efficacy of the second-generation SeQuent Please PCB in coronary ISR in routine real-world practice.

**Methods:** Between May 2009 and April 2011, all consecutive patients with ISR lesions treated with the SeQuent Please PCB at our institution were prospectively included. Patients were followed up for 24 months by clinical observation. The primary endpoint was the clinically driven target lesion revascularization (TLR) rate at 24 months. The secondary endpoint was the rate of major adverse cardiac events (MACE): defined as a composite of cardiac death, myocardial infarction, and TLR at 24 months.

**Results:** 48 patients with 52 ISR lesions (30 BMS, 22 DES) were included. Mean age was 66.2±12.3 years. 75 % were male and 50 % were diabetics. The majority of patients presented with stable angina (63.5%). The target lesion was mainly located in the right coronary artery (46.1%) and the left anterior descending coronary artery (42.3%). The mean reference vessel diameter was 3.0±0.5 mm and the mean target lesion length was 21.4±6.8 mm. Procedural success was 100 %. Coronary dissection occurred in 1 patient (1.9 %), requiring additional stent implantation. Follow-up rate was 94.2 %. The TLR rate was 5.8 % after 24 months. Cumulative MACE at 24 months was 9.6 %, with 1.9 % cardiac death and 1.9 % myocardial infarction. No vessel thrombosis was documented. The TLR rate did not differ for PCB angioplasty for BMS-ISR compared with DES-ISR (3.3% vs. 9.1%, p=0.38). Baseline lesion characteristics and procedural data did not differ except for a longer lesion length for BMS-ISR compared with DES-ISR (25.4 ±5.1 mm vs. 19.7±6.9 mm, p=0.008).

**Conclusions:** Treatment of coronary ISR with the second-generation SeQuent Please PCB provides good clinical outcomes demonstrated by the low TLR rate and low MACE rates at long-term follow-up.

**TCT-449****COMPARISON OF PACLITAXEL-ELUTING BALLOONS WITH DRUG-ELUTING STENTS FOR TREATMENT OF IN-STENT RESTENOSIS: A RETROSPECTIVE ANALYSIS OF AN ALL-COMERS COHORT**

Guillaume Marquis Gravel<sup>1</sup>, Nicolas Noiseux<sup>1</sup>, François Gobeil<sup>1</sup>, Louis-Mathieu Stevens<sup>1</sup>, Samer Mansour<sup>1</sup>

<sup>1</sup>University of Montreal, Montreal, Quebec

**Background:** The optimal treatment strategy for coronary in-stent restenosis (ISR) is unclear. Drug-eluting balloons (DEB) offer an alternative to drug-eluting stents (DES) by avoiding risks of stent thrombosis, and by lowering the risks of restenosis associated with standard balloon angioplasty and bare-metal stents. The objectives were to compare clinical outcomes of DEB versus second-generation DES for the treatment of ISR. The hypothesis was that DEB and DES would provide similar outcomes.

**Methods:** From December 2009 to November 2012, 102 coronary ISR were treated with a paclitaxel-eluting balloon in all-comer patients in a Canadian tertiary center. The comparator group consisted of a random sample of 100 patients with ISR treated with a second-generation DES in the same time period. Data was collected from medical files and telephone interviews. Mean follow-up was 16±9 months (222 patient-years). Baseline characteristics were similar between both groups (mean age: 65±11 [p=0.91]; 28% women [p=0.69]). Diabetes was present in 45% of patients (p=0.79). Indication for revascularization was non-ST-elevation acute coronary syndrome in 71% of cases in the DEB group as compared to 73% in the DES group (p=0.37).

**Results:** The composite clinical outcome of MACE (death from any cause, non-fatal myocardial infarction, or clinically-driven target-lesion revascularization) occurred in 26% of patients in the DEB group, compared to 24% in the DES group (p=0.80). Freedom from MACE was similar between both groups after adjustment for confounding factors. Secondary outcomes are shown in the Table.

**Conclusions:** DEB appears as a safe and effective treatment for ISR as compared to second-generation DES. Our data suggest that clinical outcomes following revascularization with both devices are similar. Long-term clinical outcomes following ISR treatment with a DEB compared to second-generation DES remain to be prospectively studied.

**Outcomes following treatment of in-stent restenosis**

	DEB	DES	Total	p
<b>MACE</b>	<b>25 (26%)</b>	<b>21 (24%)</b>	<b>46 (25%)</b>	<b>0.80</b>
<b>Death</b>	<b>15 (16%)</b>	<b>6 (7%)</b>	<b>21 (12%)</b>	<b>0.06</b>
<b>Non-fatal MI</b>	<b>8 (9%)</b>	<b>10 (13%)</b>	<b>18 (11%)</b>	<b>0.43</b>
<b>TLR</b>	<b>7 (8%)</b>	<b>10 (13%)</b>	<b>17 (10%)</b>	<b>0.26</b>
<b>Restenosis ≥ 50%</b>	<b>10 (11%)</b>	<b>10 (13%)</b>	<b>20 (12%)</b>	<b>0.72</b>
<b>Thrombosis</b>	<b>1 (1%)</b>	<b>1 (1%)</b>	<b>2 (1%)</b>	<b>0.93</b>
<b>Stroke/TIA</b>	<b>1 (1%)</b>	<b>1 (1%)</b>	<b>2 (1%)</b>	<b>0.96</b>

**TCT-450****PREDICTORS OF ANGIOGRAPHIC OUTCOMES FOLLOWING IN-STENT RESTENOSIS TREATMENT WITH PACLITAXEL-ELUTING BALLOONS AND SECOND-GENERATION DRUG-ELUTING STENTS.**

Guillaume Marquis Gravel<sup>1</sup>, François Gobeil<sup>1</sup>, Nicolas Noiseux<sup>1</sup>, Louis-Mathieu Stevens<sup>1</sup>, Samer Mansour<sup>1</sup>

<sup>1</sup>University of Montreal, Montreal, Quebec

**Background:** Success of in-stent restenosis (ISR) treatment depends on angiographic lesion characteristics and co-morbidities. The optimal treatment option for ISR between drug-eluting balloons (DEB) or drug-eluting stents (DES) is not well known. The objectives were to assess risk factors for adverse outcomes following ISR treatment, and to evaluate the use of DEB in this setting.

**Methods:** Multivariate binary logistic regression was performed to assess predictors of treatment success following ISR treatment in a cohort including 102 patients treated with paclitaxel-eluting balloons and 100 random patients treated with a second-generation DES between December 2009 and November 2012 in a Canadian tertiary center (mean follow-up: 16±9 months; mean age: 65±11 years). The effect of using a DEB was adjusted for angiographic and clinical confounders. Indication for revascularization was non-ST-elevation acute coronary syndrome in 145 cases (72%). Lesion localization was similar in both groups (p=0.45): 4% left main, 33% LAD, 27% circumflex, and 37% RCA. ISR pattern was focal in 62% of patients in the DEB group, compared to 46% in the DES group (p=0.02).

**Results:** Compared to diffuse, proliferative or occlusive lesions, a focal ISR was a protective factor against death (OR=0.2; p=0.01), and target-lesion revascularization (TLR) (OR=0.3; p=0.04), but not against MACE (death, non-fatal myocardial infarction [MI], and TLR) (p=0.29), MI (p=0.95), or ≥50% restenosis (p=0.19). DEB/DES length was associated with MACE (OR=1.0; p=0.03), and death (OR=0.9; p=0.001), but not with TLR, MI, and ≥50% restenosis (p>0.05 each). DEB/DES diameter was associated with none of these outcomes (p>0.05 each). Presence of chronic kidney disease (CKD) was the only identified independent risk